East Midlands Congenital Heart Centre

University Hospitals of Leicester NHS
NHS Trust

Paediatric Cardiology

Guideline for starting Aqumeldi® (Enalapril)

Staff relevant to:	Medical & Nursing staff working within EMCHC
Written by: Reviewed by:	Dr Charlotte Davidson Vicky Worthy (Pharmacist), Dr S Shebani CPG lead
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Version	1

Contents

1. Introduction and Who Guideline applies to:

This document has been produced to design a safe evidence-based guideline for the introduction of Aqumeldi® in children and young people.

Aqumeldi® contains the active substance enalapril. It is an angiotensin converting enzyme (ACE) inhibitor. The medicine blocks ACE from forming the hormone angiotensin II, which is involved in raising blood pressure. By blocking the formation of angiotensin II, Aqumeldi® helps to lower blood pressure and increase the supply of blood and oxygen to the heart.

2. Guideline Standards and Procedures

2.1 Indication:

Aqumeldi® is indicated for the treatment of heart failure in children from birth to less than 18 years.

Aqumeldi® is approved on the LLR formulary for those children unable to swallow tablets.

2.2 Contraindications:

- Concomitant use with sacubitril/valsartan - must not be given within 36 hours of switching to or from.
- Hypersensitivity to Enalapril or any other ACE*i* or to any other ingredients of Aqumeldi®

- Known history of angioedema related to previous ACE inhibitor or ARB therapy
- Hereditary or idiopathic angioedema
- Concomitant use with aliskiren-containing medications in patients with diabetes or renal impairment
- Severe renal impairment

2.3 Side effects:

- Hypotension
- Hyperkalaemia
- Cough
- Vomiting
- Microalbuminuria
- Postural dizziness

2.4 Drug Interactions requiring precautions:

- Caution with Potassium sparing diuretics – may lead to increases in serum potassium
- Caution with NSAIDs – may lead to increased risk of worsening renal function
- Caution with Lithium – may cause reversible increase in serum Lithium concentrations – careful monitoring of levels if used in combination
- Caution with mTOR inhibitor – may increase risk for angioedema

2.5 Dosage and Administration:

The initiation of Aqumeldi® should take place under health professionals' supervision under direction of the Paediatric Cardiology team.

- Baseline observations of weight, height, blood pressure, heart rate and oxygen saturations should be done prior to giving the test dose.

- Check for any allergies or adverse drug reactions.

- A baseline check of urea, creatinine and electrolytes should be done before or on the day of the first dose being administered and prior to dose increase.

Treatment should not be initiated in patients with serum potassium level >5.3 mmol/l or with SBP <5th percentile for age.

Starting/test dose:

0.01 to 0.04 mg/kg (max. 2mg) as a single initial dose

Target/maintenance dose:

0.075 to 0.15 mg/kg (max. 2.5mg) given twice a day, 8 hours after test dose

* If patient is being converted from captopril to Aqumeldi®, no test dose is required.
* To reduce tablet burden, where doses ≥2.5mg are required, consideration should be given to using standard enalapril tablets which can be crushed and dispersed in water if necessary
* Approximate conversion: - 1mg Aqumeldi® for every 7.5mg captopril

Administration:

Place on the tongue or in the buccal cavity and allow to disperse

Can be taken with or without meals

Aqumeldi® may be administered via enteral feeding tubes (see Section 2.11); flush enteral tubes with at least 3ml of water post-dose

Dosing Adjustments:

Dosing: Altered Kidney Function:

- Mild to moderate impairment (eGFR ≥30 mL/minute/1.73 m^2): Start with 50% of the single dose and dose at 12 hourly intervals
- Severe impairment (eGFR <30 mL/minute/1.73 m^2): Contraindicated

Dosing: Hepatic Impairment:

- Dose adjustment not necessary, however the treatment of children below the age of 1 month with hepatic impairment is not recommended.

2.6 Instructions for Initial dose/dose increase:

Admit to the Children's Cardiac Ward for baseline tests and observations:

- U&E's; Blood pressure, HR, oxygen saturations
- ECG
- Echocardiography- review/discuss with cardiology registrar/consultant

2.7 Clinical Care and observations during initiation

- Blood pressure should be monitored at intervals for 1– 2 hours after the initial dose and after a change in dose. Monitor blood pressure and heart rate 4 hourly after subsequent doses
- Notify medical staff of a significant drop in systolic and mean blood pressure (usually> 20 mm of Hg from base line)
- Urgent medical attention if child is symptomatic: dizzy, pale, altered level of consciousness, profound hypotension/ bradycardia, tachycardia, capillary refill > 3sec, cool peripheries.)

Hypotension:

A 20% drop in blood pressure is acceptable with a stable or upward trend in blood pressure recovery.

If the blood pressure drops greater than 20% from the baseline, firstly examine the child. If they are haemodynamically stable, well perfused and alert defer any intervention and continue to review every 15 minutes until the blood pressure increases to within 20% of the baseline. Insist on bed rest and nurse with their feet above their head.

If the child is haemodynamically unstable with a capillary refill greater than 3 seconds inform medical staff immediately and consider possible fluid bolus resuscitation. Insist on bed rest and nurse with their feet above their head. **DO**

NOT give any further doses without further discussion with medical staff.

2.8 Subsequent Dose Increases

- Patient should be admitted for each dose escalation.
- Inform parents, nurse in charge and book the patient in ward diary for next dose increase.
- Inform relevant Paediatric cardiology consultant of every admission and of any problems.
- Parents/ carer need to be educated on indication, administration and common side effects to look for: dizziness, nausea, vomiting, tiredness, dyspnoea, oedema.)
- Ensure that child has a clinic appointment following the last increment of Aqumeldi® dose.

2.9 Follow up Care

Continued monitoring is required:

- Weight, height and blood pressure at all outpatient appointments
- Blood tests: Annual U&Es – more frequently if clinically indicated

2.10 Medicinal Forms:

Aqumeldi® (Enalapril maleate) 0.25mg orodispersible tablet

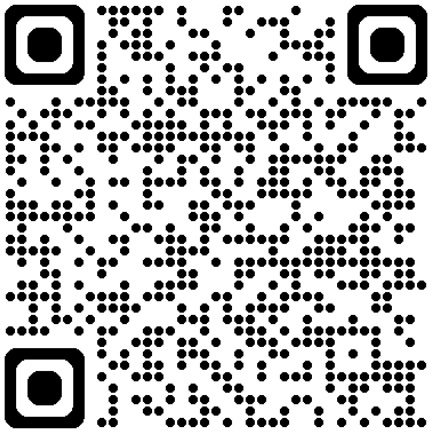
Each orodispersible tablet contains 0.25mg enalapril maleate

Available in bottles containing 50, 100 tablets

2.11 Method of administration:

- Place on the tongue or in the buccal cavity and allow to disperse
- Can be taken with or without meals

Administration support information:



Patient Information video and leaflet

Scan the QR code or click the hyperlink below

https://www.proveca.com/uk/aqumeldi-patient-information/

Special considerations:

If the dose prescribed is less than 0.25 mg:

1. Place one 0.25 mg orodispersible tablet in an oral syringe.
2. Add sterile water into the syringe up to the 2.5 mL mark.
3. Carefully roll the syringe for 3 minutes until the orodispersible tablet is fully dispersed.
4. This results in a concentration of 0.1 mg/mL enalapril maleate.
5. The required volume of dispersion should then be administered immediately to the patient; do not store the dispersion in the oral syringe

To administer via a feeding tube:

1. Remove the plunger from the syringe you use with the feeding tube and place the required number of orodispersible tablets in the barrel of the syringe. Note: a maximum of four orodispersible tablets can be dispersed in 1 mL at any one time.
2. Replace the plunger and draw up 1 mL of water. Sterile water should be used in children under 6 months of age.
3. Cap the syringe and carefully roll or mix for 3 minutes for the orodispersible tablets to disperse.

4. Remove the cap and give the dose via the feeding tube.

5. Flush the feeding tube with at least 3 mL of water after giving the medicine.

Storage:

Store in original package to protect from moisture. Do not store above 25°C.

After opening use within 100 days.

3. Education and Training

Training staff: Done by Drug providing company

Training parents and staff: QR codes for information leaflet and training video as well as link for PDF version in the references, included in this guideline.

4. Monitoring and Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Prescription dosage errors	Reported via datix	Vicky Worthy, Pharmacist/Ward Sister	Every six months	Cardiology CPM
Administration errors	Reported via datix	Vicky Worthy, Pharmacist/Ward Sister	Every six months	Cardiology CPM

5. Supporting References

1. European Medicines Agency, Summary of product characteristics, January 2024:https://www.ema.europa.eu/en/glossary-terms/summary-product-characteristics
2. https://www.proveca.com/uk/uk-products/aqumeldi/

(CTL+ Click to visit the link above)

Key Words

Aqumeldi, Enalapril, Captopril, Children's Cardiology

The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title): Dr S Shebani Paediatric Cardiologist	**Executive Lead:** Chief Medical Officer
REVIEW RECORD	
Description Of Changes (If Any) Jan 2025 Minor Amendment : Target maintenance dose changed from 0.15 to 0.3mg/kg (max 2.5mg) given once or twice daily, 8 hours after test dose to 0.075 to 0.15mg/kg (max 2.5mg) given twice a day, 8 hours after test dose.	